

REMARKS

In the present Office Action, the Examiner rejected claims 1-31. Claims 1-3, 5, 7, 9, 11, 13, 16, 18, 22, 24, 26, and 29-31 have been amended, claim 12 has been cancelled, and claims 32-40 have been added to further define the method, system, and composition of Applicants' invention. Applicants respectfully request reconsideration of claims 1-11 and 13-31 and allowance of all claims 1-11 and 13-40.

Specification

The Examiner objected to various informalities in the specification. Applicants hereby amend the specification to obviate these objections.

Claim Objections

The Examiner objected to claims 1, 11, and 12 for informalities. Applicants have herein amended claims 1 and 11 to correct the minor informalities and cancelled claim 12, and therefore request reconsideration and withdraw of the claim objections.

35 U.S.C. 112 Rejections

Claim 12 is rejected under 35 U.S.C. 112. Applicants herein cancel claim 12, thus obviating this rejection.

35 U.S.C. 102 Rejections

Claims 1, 2, 11-15, and 27-29 stand rejected under 35 U.S.C. 102 as being anticipated by Davidson et al. (U.S. Patent No. 6,365,624). Applicants respectfully request reconsideration and withdrawal of this rejection.

Claim 1 has been amended to recite a "decongestant selected from the group consisting of oxymetazoline hydrochloride, naphazoline hydrochloride, ephedrine, phenylephrine hydrochloride, xylometaxoline hydrochloride," which is nowhere taught in Davidson et al. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection to claim 1 and claim 2 that depends therefrom.

Similarly, claim 11 recites "active substance selected from the group consisting of oxymetazoline hydrochloride, naphazoline hydrochloride, ephedrine, phenylephrine

hydrochloride, and xylometaxoline hydrochloride,” which is nowhere taught cited reference. Applicants therefore request reconsideration and withdrawal to this rejection to claim 11 and claims 14-15 that depend therefrom.

Claims 27 and 28 include the composition limitations set forth in claims 1 and 11 respectively. Accordingly, Applicants submit that claims 27 and 28 are allowable over Davidson et al.

Finally, claim 29 also includes “decongestant selected from the group consisting of oxymetazoline hydrochloride, naphazoline hydrochloride, ephedrine, phenylephrine hydrochloride, and xylometaxoline hydrochloride,” which is nowhere taught by the cited reference. Applicants thus request withdrawal of this rejection with respect to claim 29.

35 U.S.C. 103 Rejections

Claims 3-10 and 16-26 stand rejected under 35 U.S.C. 103 as being unpatentable over Davidson et al. in view of Haslwanter et al. (U.S. Patent No. 5,854,269). Applicants respectfully request reconsideration of this rejection in view of the amendments and remarks set forth herein.

As a preliminary matter, Applicants submit that there is no suggestion or motivation in the references, to modify the references or to combine references' teachings. Davidson et al. discloses a method of applying a zinc ion gel to a nasal membrane. The composition has a viscosity and carrier configured to maintain the zinc ions in contact with the nasal membrane for an extended period of time. In contrast, Haslwanter et al. discloses an aqueous composition including oxymetazoline to treat nasal decongestion. Haslwanter does not teach or suggest applying the oxymetazoline via a viscous gel. Further, nothing in the reference suggests that maintaining the oxymetazoline in contact with a nasal membrane for an extended period of time (as opposed to facilitating rapid delivery to the blood stream) has any benefit.

Furthermore, no combination of the references teaches or suggests all the claim limitations. In particular, the combination does not teach or suggest “about 0.001 to about 5.0 weight percent of a decongestant selected from the group consisting of oxymetazoline hydrochloride, naphazoline hydrochloride, ephedrine, phenylephrine hydrochloride, xylometaxoline hydrochloride, wherein the composition has a viscosity greater than about 2,500 centipoise,” as set forth in claim 1, from claims 3-10 depend.

Neither reference discloses or suggests this particular viscosity limitation or a viscous composition containing these active ingredients. Accordingly, Applicants request reconsideration and withdrawal of this rejection to claims 3-10.

Similarly, no combination of the references teaches or suggests "about 0.000001 to about 10 weight percent an active substance selected from the group consisting of oxymetazoline hydrochloride, naphazoline hydrochloride, ephedrine, phenylephrine hydrochloride, and xylometaxoline hydrochloride, wherein the composition has a viscosity from about 3,000 centipoise to about 10,000 centipoise," as set forth in claim 11, from which claims 16-23 depend. Applicants therefore request reconsideration and withdrawal of this rejection to claims 16-23.

Finally no combination of the references teaches or suggests "about 0.001 to about 1.0 weight percent of a decongestant comprising oxymetazoline hydrochloride... wherein the composition has a viscosity from about 2,500 centipoise to about 40,000 centipoise," as set forth in claim 24, from which claims 25-26 depend. Applicants thus request reconsideration and withdrawal of this rejection to claims 24-26.

Claims 30-31 stand rejected under 35 U.S.C. 103 as being unpatentable over Davidson et al. in view of Haslwanter et al., in further view of Pier (U.S. Patent No. 6,245,735). Applicants respectfully request withdrawal of this rejection.

As noted above, there is no motivation to combine Davidson et al. and Haslwanter et al. and there is no suggestion that the combination would be successful. Further, there is no motivation to combine Pier with Davidson et al., Haslwanter et al. or the combination of the references.

Pier is directed to methods and products for upregulating cystic fibrosis transmembrane conductance regulators. Nowhere does Pier teach or suggest that liposomes are suitable in viscous cold remedy formulas including oxymetazoline hydrochloride.

Indeed, no combination of the cited references teaches or suggests a permeation enhancer comprising liposomes as set for in both claims 30 and 31. Moreover, no combination teaches or suggests "about 0.001 to about 5.0 weight percent of an active ingredient comprising oxymetazoline hydrochloride... wherein the composition has a viscosity between about 2,500 and about 40,000 centipoise," as set forth in claim 30 or

“about 0.001 to about 5.0 weight percent of an active ingredient comprising oxymetazoline hydrochloride... wherein the composition has a viscosity between about 2,500 and about 40,000 centipoise,” as set forth in claim 31. Applicants therefore request reconsideration and withdrawal of this rejection to claims 30 and 31.

Double Patenting

Claim 29 stands provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-11 of copending Application No. 10/664,839 and claims 1 and 11 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23-29 and 34 of copending Application No. 11/028,991. Applicants acknowledge the Examiner's assertion, but submit that no action is required at this time.

New Claims


New claims 32-35 are patentable over the cited references because the claims they depend from (1 and 11) are patentable. Further, claims 36-40 are allowable over the art of record because no combination of the references teaches or suggests “a composition having about 75 to about 99.999 weight percent of a carrier and about 0.000001 to about 10 weight percent an active substance selected from the group consisting of oxymetazoline hydrochloride, naphazoline hydrochloride, ephedrine, phenylephrine hydrochloride, and xylometaxoline hydrochloride, wherein the composition has a viscosity greater than about 2,500 centipoise and less than about 40,000 centipoise,” as set forth in claim 36-39 or “about 0.045 wt % to about 0.055 wt % oxymetazoline...[and] about 0.000001 to about 5.0 wt % thickener” as set forth in claim 40

Conclusion

Applicants respectfully submit that all pending claims are patentable and therefore respectfully request allowance of all claims. Should the Examiner have any questions regarding this Amendment and Response, the Examiner is invention to call the undersigned at the number provided below.

Respectfully submitted,

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